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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/865,321	05/23/2001	Robert J. Peach	D0028PNP;30436.57USU1	2959
23914	7590	09/27/2004	EXAMINER	
STEPHEN B. DAVIS BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT P O BOX 4000 PRINCETON, NJ 08543-4000			OUSPENSKI, ILIA I	
			ART UNIT	PAPER NUMBER
			1644	
DATE MAILED: 09/27/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/865,321

**Applicant(s)**

PEACH ET AL.

**Examiner**

ILIA OUSPENSKI

**Art Unit**

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2004 and 19 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 67-96, 104-109, 113 and 114 is/are pending in the application.
- 4a) Of the above claim(s) 81-85 and 87-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 67-80, 86, 95, 96, 104-109, 113 and 114 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Ilia Ouspenski, Group Art Unit 1644, Technology Center 1600.

2. Applicant's amendments, filed 06/07/2004 and 07/19/2004, are acknowledged and have been entered.

Claims 94, 97 – 103, 110 – 112, and 115 have been cancelled.

Claims 1 – 66 have been cancelled previously.

Claims 67 – 80, 86, 95 – 96, 104 – 108, and 113 - 114 have been amended.

Claims 81 – 85 and 87 – 94 have been withdrawn.

Claims 67 – 96, 104 – 109, and 113 - 114 are pending.

*Claims 67 – 80, 86, 95 – 96, 104 – 109, and 113 - 114 are under consideration in the instant application.*

3. This Office Action will be in response to applicant's arguments, filed 11/26/2003, 01/05/2004 and 03/23/2004.

The rejections of record can be found in the previous Office Actions.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

4. Specification and Claim Objections: Applicant's amendments to the specification and claims have obviated the objections of record.

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5. Claim Rejections – 35 USC §112 first paragraph: Applicant's provision of the required assurances and showing that the Deposit was made under the terms of the Budapest Treaty have obviated the rejection of record.

6. Claim Rejection – 35 USC §102(b): Claims 67 – 80, 86, 95 – 96, 104 – 109, and 113 – 114 are rejected under 35 USC §102(b) as being anticipated by Peach et al. (of record, see entire document) as evidenced by Cohen et al. (of record, see entire document).

Applicants arguments have been fully considered, but were found only partially convincing.

Applicant argues that the molecule disclosed by Peach et al. (WO 98/33513) is distinct from the instantly claimed invention, because its disclosed amino acid sequence is different, even though it is referred to by the same name (LEA29Y).

It remains unclear, however, which of the two definitions of molecular identity is correct: either (a) the same molecule is disclosed as having two different amino acid sequences in Peach et al. (WO 98/33513) and in the instant application, e.g. due to a sequencing error, or (b) two different molecules have been given the same name by the same group of Inventors. No objective evidence that the LEA29Y molecule taught by Peach et al. is different the instantly claimed LEA29Y molecule has been presented by the Applicant.

Absent any factual evidence to clarify the identity of the claimed molecule, the rejection is maintained essentially for the reasons of record.

The rejection of record is reiterated below:

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Peach et al. teach soluble CTLA4 mutant molecules (see entire document, e.g., Abstract).

Peach et al. teach the mutant molecule LEA29Y (page 7, especially lines 26-32). LEA29Y is a soluble CTLA4 mutant molecule which has a higher affinity for CD86 (see Figure 1). Pharmaceutical compositions comprising the mutants are also taught (pages 11-12).

Cohen et al. evidence that LEA29Y is the same molecule as the instant L104EA29YIg mutant whose amino acid sequence is set forth in instant SEQ ID NO:4 and shown in instant Figure 7. In particular, Cohen et al. teach at paragraph 237 that L104EA29YIg is also known as LEA29Y, provide the amino acid sequence of L104EA29YIg in Figure 19, and teach that it is encoded by the nucleic acid deposited as ATCC No. PTA-2104 (see paragraph 84). The amino acid sequence shown in Figure 19 of Cohen et al. is identical to instant SEQ ID NO:4, the amino acid sequence shown in instant Figure 7 and the amino acid sequence encoded by the nucleic acid deposited as ATCC No. PTA-2104.

The Examiner acknowledges that WO98/33513 teaches that the sequence of LEA29Y is set forth in SEQ ID NO:1 (where Xaa is "Y" and Yaa is "E"), and that the amino acid sequence of SEQ ID NO:1 is not the same as instant SEQ ID NO:4 or the amino acid sequence set forth in instant Figure 7.

However, the amino acid sequences provided in WO98/33513 as Figure 7 and SEQ ID NO:1 are inconsistent with the description of the positions mutated in the CTLA4 sequence provided on page 19 of WO98/33513. For example, page 19 identifies the CDR1 loop of CTLA4 as S25 to R33, whereas Figure 7 has S26 and R34. The ordinary artisan at the time the invention was made would therefore have recognized that the numbering and identity of the amino acids mutated to generate the CTLA4 mutant molecules taught by Peach et al. on page 19 of WO98/33513 establish a discrepancy in the sequences set forth in SEQ ID NO:1 and Figure 7 of WO98/33513, particularly in view of the references provided in WO98/33513.

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Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed limitations would be inherent properties of the LEA29Y mutant.

The reference teachings thus appear to anticipate the instant claimed invention.

7. Double Patenting: The provisional rejection of record over copending Application USSN 09/898,195 has been obviated by cancellation of the relevant claims in the copending application.


8. Conclusion: No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI  
Patent Examiner  
Art Unit 1644

  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
TECH CENTER 1600  
9/24/09

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September 17, 2004